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US006203556B1

(12) **United States Patent**
Evans et al.

(10) Patent No.: **US 6,203,556 B1**
(45) Date of Patent: ***Mar. 20, 2001**

(54) TRANSMYOCARDIAL REVASCULARIZATION SYSTEM AND METHOD OF USE

(75) Inventors: Douglas G. Evans, Downingtown; John E. Nash, Chester Springs, both of PA (US)

(73) Assignee: Kensey Nash Corporation, Exton, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 09/369,107

(22) Filed: Aug. 5, 1999

Related U.S. Application Data

(63) Continuation of application No. 08/958,788, filed on Oct. 29, 1997, now Pat. No. 5,980,548.

(51) Int. Cl.[7] A61B 17/34
(52) U.S. Cl. 606/185; 606/220
(58) Field of Search 606/185, 213, 606/159, 220, 7, 15; 623/3.11, 3.26, 11; 128/898

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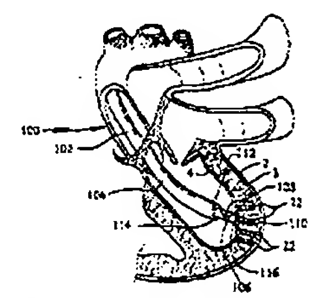
(57) ABSTRACT

A transmyocardial revascularization system including a plurality of inserts formed of a material to elicit a healing response in tissue of the myocardium and deployment instruments and associated components for deploying the inserts into the wall of the myocardium. The inserts are arranged to be disposed within respective lumens or channels in the wall of the myocardium. The inserts can take various forms, e.g., be solid members, tubular members, or porous members, and may be resorbable, partially resorbable or non-resorbable. In some embodiments the inserts are arranged to be left in place within the channels in the wall of the myocardium to result in plural lumens which enable blood to flow therethrough and into contiguous capillaries. The deployment instruments are arranged to pierce the tissue of the myocardium from either the endocardium or the epicardium to insert the inserts into the myocardium, depending on the particular deployment instrument used. The deployment instruments may make use of a stabilizing device to stabilize them during the procedure of inserting the inserts into the myocardium. A controller may also be provided as part of the system to coordinate the operation of the deployment instrument with the cardiac cycle. The formation of the lumens can be achieved either by the inserts or by some other means, such as a piercing tip or an energy applicator forming a portion of the instrument. The inserts may include one or more of pharmaceuticals, biologically active agents, radiopaque materials, etc.

19 Claims, 10 Drawing Sheets



See Fig. 9F

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United States Patent [19]

Ray et al.

[11] Patent Number: 4,961,740

[45] Date of Patent: Oct. 9, 1990

[54] V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT

[75] Inventors: Charles D. Ray, Deephaven; Eugene A. Dickhudt, New Brighton, both of Minn.

[73] Assignee: Surgical Dynamics, Inc., Alameda, Calif.

[21] Appl. No.: 259,031

[22] Filed: Oct. 17, 1988

[51] Int. Cl.⁵ A61F 5/04; A61F 2/28

[52] U.S. Cl. 606/61; 606/86; 623/16

[58] Field of Search .... 128/92 YJ, 92 C, 92 CA, 128/92 UP, 92 YP, 92 YZ; 623/16, 17, 18

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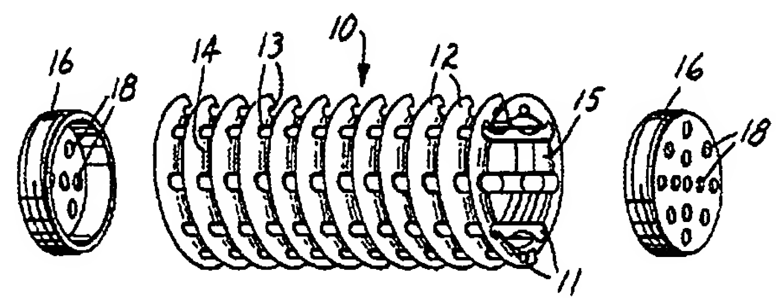
Primary Examiner—Robert A. Hafer
Assistant Examiner—Kerry Owens
Attorney, Agent, or Firm—Fliesler, Dubb, Meyer & Lovejoy

[57] ABSTRACT

A fusion cage 10 includes a cage body defining an internal cavity with an inner surface and an outer surface. The outer surface defines a helical thread 12 comprised of a plurality of turns which define valleys 14 therebetween. Located in the valleys 14 are perforations 13 which provide communication between the outer surface and the interior cavity. Thus, when the fusion cage 10 is mated to a bone structure and the internal cavity is packed with bone chips or other bone-growth-inducing substances, there is immediate contact between the bone structure and the bone chips through the perforations 13.

34 Claims, 1 Drawing Sheet



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160	US 5059654 A		USPAT	19911022	51	US 5059

thread has from 3 to 8 turns per cm. A smaller turn ratio may result in an undesirably large thread depth, penetrating too deeply into the cancellous bone. A larger turn ratio may unduly restrict the size of the perforations.

The novel V-thread fusion basket can be implanted for fixing adjacent bony structures by the following method:

(a) forming in said bony structures a bore with a female thread that penetrates into their cancellous regions,

(b) forming a rigid, perforate, cylindrical basket to have an external, substantially continuous helical V-thread that can mate with said female thread,

(c) screwing the basket into said threaded bore, and

(d) packing the basket with bone-inducing substance. When the bore to be formed in step (a) is to extend between adjacent vertebrae, there should be prior to step (a) the added step of spreading the vertebrae apart, preferably in a manner that maintains their parallelism, the fusion basket is implanted in pairs on opposite sides of the disc space.

The novel fusion basket should have a modulus of elasticity approximating that of the recipient bone, thus permitting it to flex along its length, consequently minimizing stresses at the bony interface between the graft and recipient bone. Although a fusion basket of substantially lower modulus of elasticity would provide the same desirable result, it might not have adequate structural strength.

The bore into which the V-thread fusion basket is to be inserted preferably is tapped by hand, using a slow motion to ensure against burning the bone. This freshens the bone margins of the bore so that if any bone had been burned by drilling to form the bore, it is now cut away slowly by hand. The tapping process is quite safe, in that the surgeon can feel the progress of the technique.

The V-thread fusion basket preferably is screwed by hand into the threaded bore, again permitting the surgeon to feel if the resistance is too great and that rethreading of the bore might be required. In contrast, a bone dowel typically is driven into a bore using a hammer, and in order to guard against an overly tight fit, the surgeon listens to the sound of the striking hammer and also monitors the degree of resistance.

When using the novel fusion basket to create bone ingrowth between adjacent vertebrae, the fusion basket should be implanted in pairs on opposite sides of the disc space. Each is held in place by its V-thread, biting into female threads that penetrate into the cancellous bone of the interposed vertebral bodies. Gravity, muscle pull and elastic recoil of the spread (or stretched) outer disc anulus together exert force against each of the fusion baskets. Thus the fusion baskets are held in place by compression forces between the adjacent vertebrae.

To prevent distraction forces from possibly dislodging the fusion baskets, e.g., when the patient forward flexes, thus separating the posterior margins of the adjacent vertebrae, the dorsal processes may be tied or wrapped together. By another technique, screws placed through the appropriate facet jackets limit both flexion and extension motions.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument. Another instrument that has been developed for use in the implantation of the novel fusion basket is a tapping instrument for forming helical threads in a bore in recipient bone. This novel tapping instrument comprises

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft. The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir.

When using the novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three, because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

The novel tapping instrument and a novel wrench are illustrated in the drawing that also illustrates two V-thread fusion baskets of the invention.

THE DRAWING

In the drawing, all figures of which are schematic,

FIG. 1 is an exploded isometric view of a first V-thread fusion basket of the invention and two perforated end caps;

FIG. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion baskets of the invention;

FIG. 3 is an isometric view of a tap (partly cut away to reveal details of construction) for forming female threads in bores into which a V-thread fusion basket is to be inserted; and

FIG. 4 is an isometric view of a wrench for screwing a V-thread fusion basket into a threaded bore.

The fusion basket 10 of FIG. 1 was formed from a solid steel cylinder by drilling eight small, equally spaced holes 11 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion basket to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps would also be useful.

In making a fusion basket by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole. Enlarged small holes would result in larger perforations 13.

Referring to FIG. 2, a series of fusion baskets can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangu-

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159	US 5055104 A		USPAT	19911008	9	US 5055
160	US 5059654 A		USPAT	19911022	51	US 5059

lar rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion baskets each of which has a perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion basket identical to that of FIG. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion baskets of FIGS. 1 and 2 could be made from a model by the lost wax process.

The tapping instrument 30 of FIG. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end. Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown) to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads in the bore upon rotation of the hollow shaft.

Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry detritus upwardly to be deposited through the scallops into the reservoir.

Upon rotating the hollow shaft 31 to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to complete the tapping.

The wrench 40 of FIG. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion basket to permit the fusion basket to be rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion basket.

IMPLANTING THE FUSION BASKET

In order to implant the novel fusion basket between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminae of each side, namely, standard laminotomies. The neural tissues, dural sac and nerves, are retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x-ray. The height of the disc space is measured on the x-ray so that the proper sizes of drills, tap, and fusion basket may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the intradiscal space to a depth of about 25 mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of FIG. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion basket of the invention, with one end cap in place, is snapped onto the wrench 40 of FIG. 4 by which it is screwed by hand into the threaded intradiscal bore to its full depth. After removing the wrench, the basket is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion basket by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion baskets and unite with the bone-inducing substance inside them, creating a solid fusion.

It is believed that the novel fusion baskets will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the cervical spine.

EXAMPLE 1

The fusion basket of FIG. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions

diameter of starting cylinder	16	mm
length of cylinder	25	mm
diameter of each small hole 11	3	mm
diameter of circle on which holes 11 are centered	11.5	mm
diameter of central hole	11	mm
pitch of V-thread 12	3.5	mm/turn
angle at crown of thread 12	60°	
fillet radius in valley of thread 12	0.4	mm
axial width of perforations 13	1.6	mm
circumferential breadth of perf. 13	2.6	mm
when projected onto exterior of a cylinder, % of area perforated	25%	

A V-thread fusion basket identical in appearance to one produced as in FIG. 2 can be made from a hollow cylindrical tube. After machining an external thread, a plurality of rectangular keyways are broached in the inner surface to form perforations through the valley of the thread. A continuous technique for making a novel fusion basket starts with a continuous helical spring made from a triangular rod such as the rod 26 used in FIG. 2, then welding or soldering the inner-facing sur-

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Detailed Description Text - DETX (2):

FIG. 1 shows a bottom, plan view of an electrode according to the present invention. The electrode is provided with an insulative electrode pad 10, corresponding to the electrode pad illustrated in the above-cited U.S. Pat. No. 4,817,634, issued to Holleman et al. incorporated herein by reference in its entirety. The pad 10 is a generally planar structure fabricated of silicone rubber, polyurethane or other flexible insulative biocompatible plastic. It is provided with a plurality of concentric, oval shaped grooves into which the braided carbon fiber electrodes are mounted.

Detailed Description Text - DETX (4):

The lead of FIG. 1 is provided with four separate carbon fiber electrodes 14, 16, 18 and 20. Each of these electrodes takes the form of tubular braid of metallized carbon fibers, each laid in one of the oval shaped, concentric grooves in electrode pad 10. Each of the carbon fiber electrodes 14, 16, 18 and 20 is provided with an inner tubular core of silicone rubber, around which the tubular braid of carbon fibers is mounted. The carbon fibers are retained within the grooves in base pad 10 by means of medical adhesive, which bonds the tubular core within the carbon fiber braids to the pad 10.

Detailed Description Text - DETX (6):

FIG. 2 is a diagram of an alternate embodiment of a lead employing the present invention. It too is provided with an electrode pad 110 which corresponds to pad 10 in FIG. 1. Pad 110 is similarly provided with a dacron enforcement mesh 112 around its external periphery. In the electrode FIG. 2, only one carbon fiber electrode 114 is provided, mounted to the grooves within pad 110 to provide a spiral shaped electrode. On exiting the electrode pad, electrode 114 is provided with a insulative sheath 112 which extends to the proximal end of the lead.

Detailed Description Text - DETX (9):

FIG. 5 is an illustration of yet another embodiment of an electrode according to the present invention, in which the weaving techniques employed to produce bifurcated tubular structures in the context vascular grafts have been applied to the context of implantable defibrillation leads. As illustrated, a single, large diameter tubular carbon fiber braid 430 is split into two smaller segments and then split again to form four parallel tubular segments 414, 416, 418 and 420. Mounted within segments 414, 416, 418 and 420 are silicone rubber or other plastic core members. The tubular carbon fiber braid may be backfilled with silicone rubber in other areas, in order to prevent tissue ingrowth into the braid in the areas of the bifurcations. The large diameter braid 430 is covered with an insulative sheath 422, extending to the proximal end of the lead, at which point an electrical connector is mounted to braid 430. As illustrated, the carbon fiber electrode structure is mounted to a flexible, insulative backing member 410, which may be provided with grooves corresponding to the desired configuration of the carbon fiber electrode. As in the embodiments illustrated in FIGS. 1 and 2, the carbon fiber electrode may be retained within the grooves by means of silicone rubber medical adhesive. Alternatively, the backing member 410 may be dispensed with, and the electrode used without a backing member, either subcutaneously or epicardially in a manner analogous to the electrode illustrated in FIG. 3.

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13	US 6217610 B1		USPAT	20010417	36	US 6217
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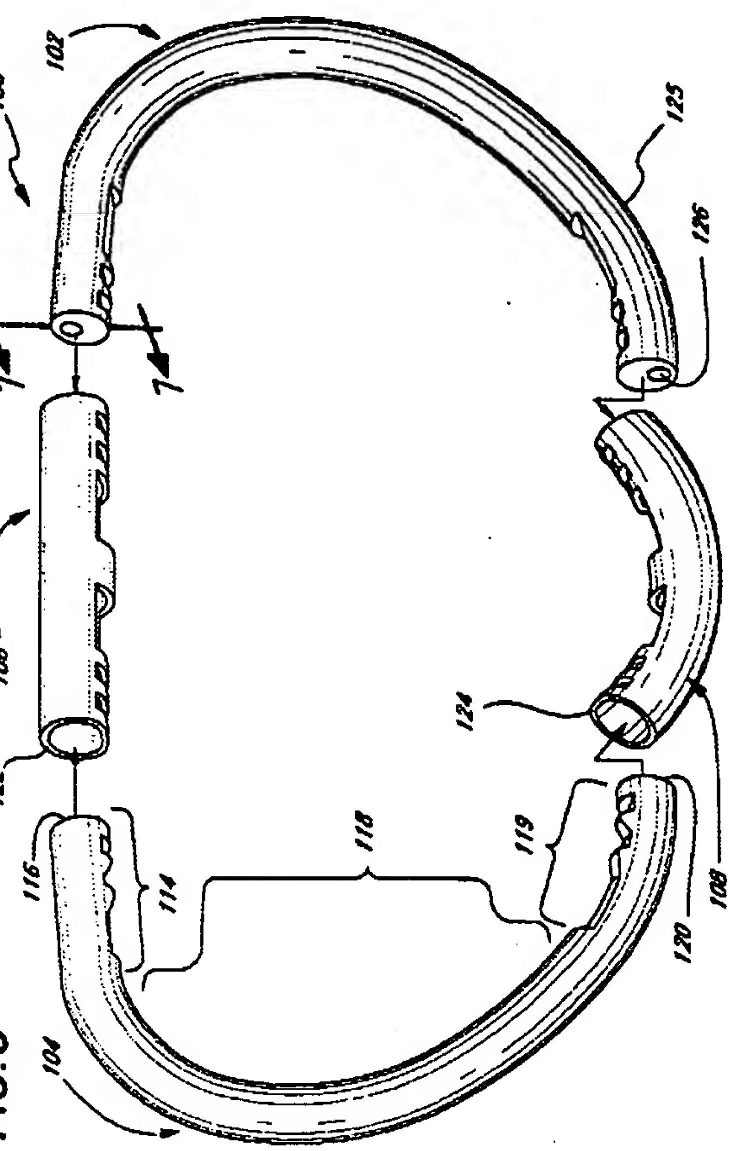

FIG. 6

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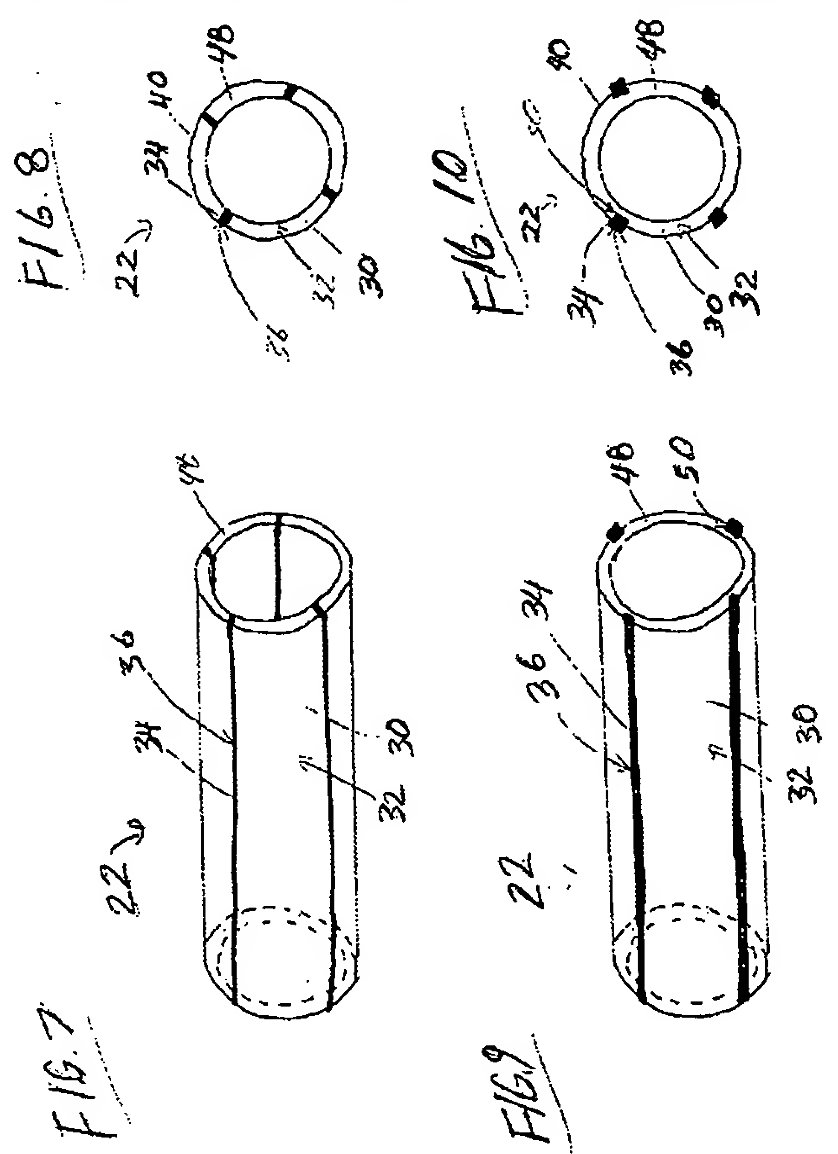

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SURGICAL PROSTHESIS

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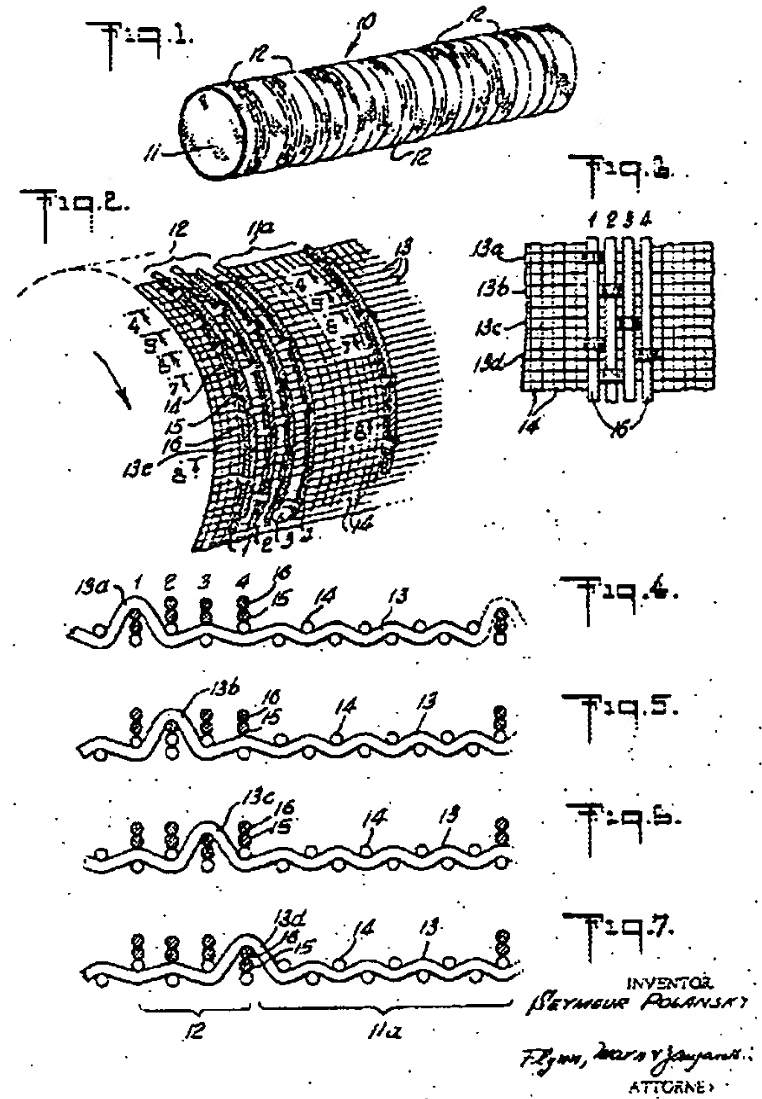

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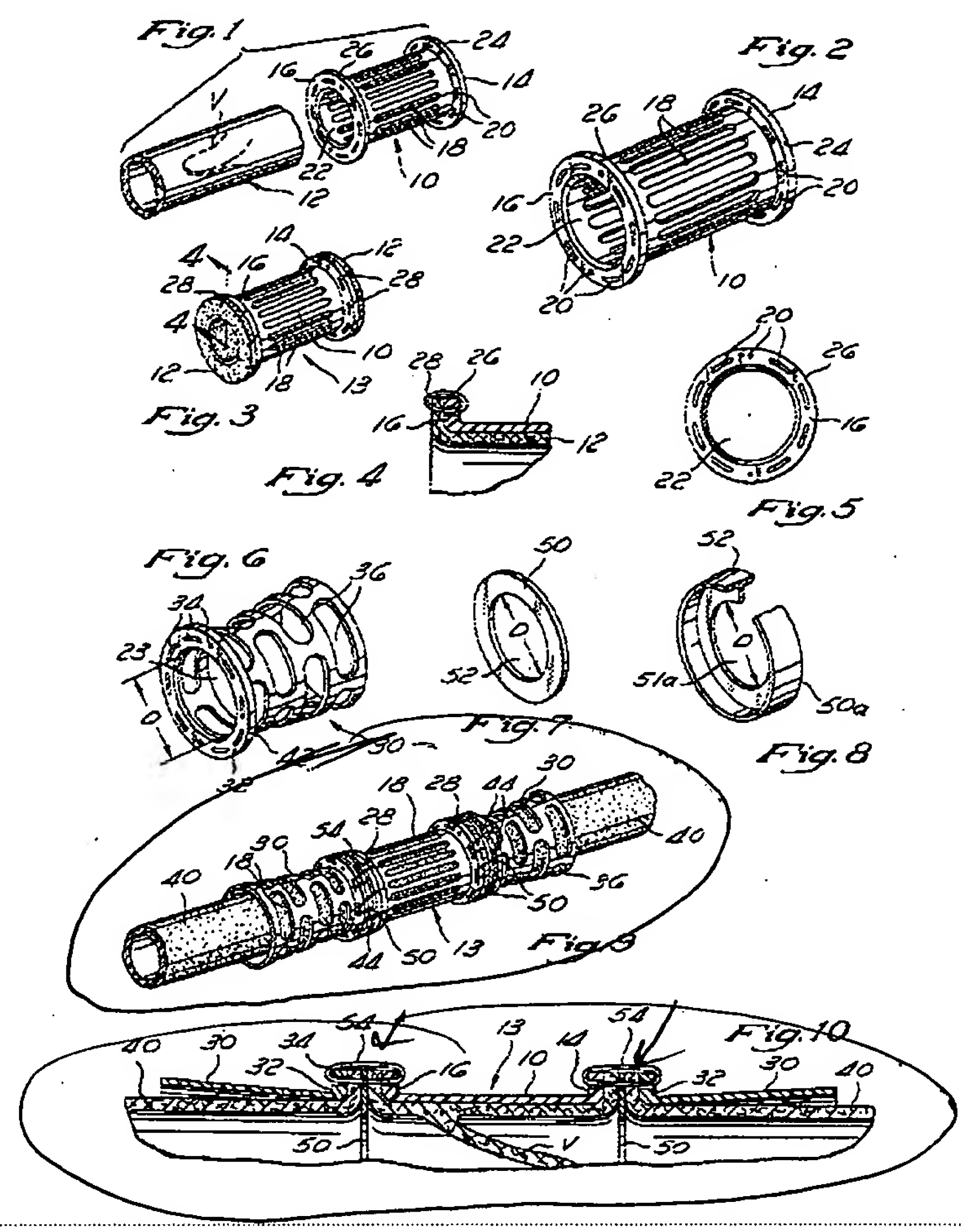

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(54) ADVANCED ENDOVASCULAR GRAFT

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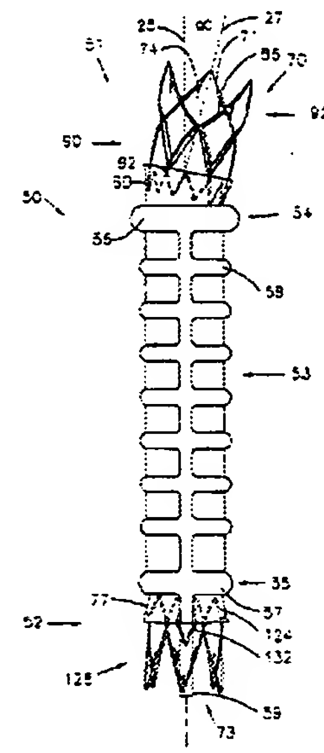
(52) U.S. Cl. 623/1.13; 623/1.25; 623/1.36

(57) ABSTRACT

This invention is a system for the treatment of body passageways; in particular, vessels with vascular disease. The system includes an endovascular graft with a low-profile delivery configuration and a deployed configuration in which it conforms to the morphology of the vessel or body passageway to be treated as well as various connector members and stents. The graft is made from an inflatable graft body section and may be bifurcated. One or more inflatable cuffs may be disposed at either end of the graft body section. At least one inflatable channel is disposed between and in fluid communication with the inflatable cuffs.



EAST Browser - L11: (33) 9 and (grooves) | US 20030120331 A1 | Tag: S | Doc: 18/33 (SORTED) | Format : KWIC

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1	US 5628786 A		USPAT	19970513	10	US 56287
2	US 5873904 A		USPAT	19990223	24	US 58739
3	US 6077217 A		USPAT	20000620	14	US 60772
4	US 6159239 A		USPAT	20001212	41	US 61592
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25	US 6656215 B1		USPAT	20031202	26	US 66562
26	US 6673102 B1		USPAT	20040106	27	US 66731
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DOCUMENT-IDENTIFIER: US 20030120331 A1

TITLE: Advanced endovascular graft

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Current US Classification, US Primary Class/Subclass - CCPR (1):
623/1.13

Summary of Invention Paragraph - BSTX (18):
[0017] In addition, the stent may comprise grooves. In a typical delivery system, some type of belts or sutures may be used to help retain the endovascular graft in its compressed delivery configuration. The grooves may accommodate these belts or sutures without increasing the small diameter delivery of the device.

Detail Description Paragraph - DETX (29):
[0083] During preparation of graft 10 (and therefore proximal stent 40) into its reduced diameter delivery configuration, each barb 43 is placed behind a corresponding strut 41 (and optional tuck pad 45, if present) so to thereby prevent that barb from contacting the inside of a delivery sheath or catheter during delivery of the device and from undesired contact with the inside of a vessel wall. As described in copending U.S. patent application Ser. No. 09/917,371 to Chobotov et al., a release belt disposed in one or more grooves 35 disposed on struts 41 retain proximal stent 40 in this delivery configuration.

Detail Description Paragraph - DETX (38):
[0092] Proximal stent 70 also may comprise one or more sets of optional grooves 87 for housing device release bands as previously discussed.

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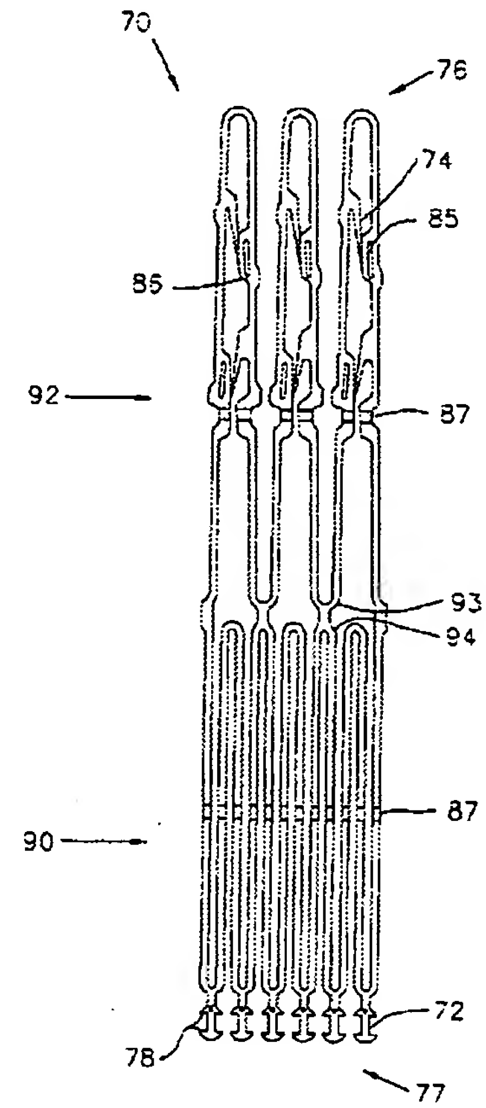

FIG. 4